REMARKS/ARGUMENTS

Claims 1, 4 and 9-12 are in this application. Claims 2-3 and 5-8 are cancelled without prejudice. Claims 9-12 are new and depend ultimately from claim 1.

The examiner has acknowledged that claim 4 is directed to allowable subject matter.

In view of the examiner's earlier restriction requirement, applicant retains the right to present claims 5-8 in a divisional application.

Claim 1 has been amended for clarity and to incorporate subject matter from claims 2 and 3. The claim dependency of claim 4 has been amended in view of the cancellation of claim 2.

Support for new claims 9 and 11 may be found, for example, on page 4, line 20. Support for new claims 10 and 12 may be found, for example on page 4, lines 3-5.

Claim Rejections – 35 USC § 112

Examiner has rejected claims 1-3 as being indefinite in respect of the term "es-LAPase". Claim 1 has been amended to replace this term with the phrase "estrogen-stimulated isoenzyme of leucine aminopeptidase". Support may be found, for example, on page 4 of the description.

Examiner has interpreted "es-LAPase" to mean "serum leucine aminopeptidase", and has based the Office Action on that interpretation. However, the estrogen-stimulated isoenzyme of leucine aminopeptidase recited in the present claims does not encompass all serum leucine aminopeptidases. As discussed in the description on page 4, the isoenzyme recited in the present claims is different from other isoenzymes reported in the literature. The present isoenzyme is specifically activated in a dose-dependent manner by an estrogen (page 4, lines 7-25), and is present not only in serum, but also blood, plasma and tissue (page 4, lines 3-5).

Claim 1 has also been amended to replace "the" with "a" at the first occurrence of the term "level".

Claim Rejections – 35 USC § 102

Examiner has rejected claims 1-3 as being anticipated by Gupta et al. Applicant traverses having regard to the amended claims and the following comments.

The present claims recite a method of detecting breast cancer using an immunoassay method. They further recite determining the level of an estrogen-stimulated isoenzyme of leucine aminopeptidase, and determining such a level by an immunoassay using a monoclonal antibody specific for the isoenzyme. Such features are not disclosed by Gupta et al.

Claims 9 and 11 are further distinguished from Gupta et al. since Gupta et al. does not disclose an estrogen-stimulated isoenzyme of leucine aminopeptidase having a molecular weight of 315 kDa.

Withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 USC § 103

Examiner has rejected claims 1-3 as being unpatentable over Gupta et al. in view of Deng et al. Applicant traverses having regard to the amended claims and the following comments.

Neither Gupta et al. nor Deng et al. teach an immunoassay method of detecting breast cancer. Neither Gupta et al. nor Deng et al. teach an estrogen-stimulated isoenzyme of leucine aminopeptidase. Neither Gupta et al. nor Deng et al. teach a monoclonal antibody specific for such an isoenzyme. Therefore, the combination of Gupta et al. and Deng et al. cannot make obvious the claimed invention which recites these features.

Gupta et al. teaches measuring the activity of serum leucine aminopeptidase (serum LAP) by a chemical method (see page 302). There is no teaching of an immunoassay method generally, and no teaching of a method based specifically on determining levels of an estrogen-stimulated isoenzyme of leucine aminopeptidase. Applicant's claimed method involving specific detection of an estrogen-stimulated isoenzyme of leucine aminopeptidase is much more sensitive than the method taught by Gupta et al. (compare Example 5, Tables 3 and 4 of the present specification to page 302-303 and Table 1 of Gupta et al.). In Applicant's method, the relative difference between control values and positive values is several orders of magnitude, whereas the relative difference in Gupta et al.'s method is only a factor of about 2.

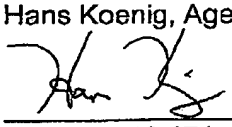
The teachings of Deng et al. do not relieve the deficiencies of Gupta et al. Deng et al. merely teaches that the antigen to AD-1 antibody is a membrane bound serum leucine aminopeptidase (serum LAP), and that this fact can be exploited to diagnose and monitor cholestatic liver disease. There is no teaching or suggestion in Deng et al. of an estrogen-stimulated isoenzyme of leucine aminopeptidase. Further, there is no teaching or suggestion that a leucine aminopeptidase could be used in an immunoassay for breast cancer. Furthermore, there is no teaching or suggestion that a leucine aminopeptidase could be used in an immunoassay for breast cancer that provides more sensitive results than the chemical method taught by Gupta et al.

Claims 9 and 11 are further distinguished from Gupta et al. and Deng et al. since neither reference discloses an estrogen-stimulated isoenzyme of leucine aminopeptidase having a molecular weight of 315 kDa.

Applicant respectfully requests that the rejection be withdrawn.

In view of the above amendment and remarks, reconsideration on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
Hans Koenig, Agent for Applicant



Reg. No. 46,474
Tel.: (519) 430-7169

Date: January 2, 2007